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Pesticide Assessment Guidelines, Subdivision O Residue Chemistry, Specialty Applications (Addendum 5 to Data Reporting)

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PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION O

RESIDUE CHEMISTRY

Series 171-4

Specialty Applications

(I) Classification of Seed Treatments and Treatment of Crops Grown for Seed Use Only as Non-Food or Food Uses

(II) Magnitude of the Residue: Post-harvest Fumigation of Crops and Processed Foods and Feeds

(III) Magnitude of the Residue: Post-harvest Treatment (Except Fumigation) of Crops and Processed Foods and Feeds

ADDENDUM 5 ON DATA REPORTING

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ADDENDUM 5 to Pesticide Assessment Guidelines, Subdivision O, Hazard Evaluation: Residue Chemistry (EPA-540/9-82-023 and NTIS Order Number PB83-153961), October, 1982

16. Abstract (Limit: 200 words)

The Data Reporting Guideline (DRG) for Specialty Applications, Series 171-4, gives guidance to pesticide registrants on formats for study reports so that the Agency can review them efficiently. This guidance clarifies sections in the existing Pesticides Assessment Guidelines, Subdivision O, on data reporting. It provides an outline for the study report, describes the topics which should be addressed and provides guidance on data presentation. This DRG actually contains formats for three study reports:

I Classification of Seed Treatments and Treatment of Crops Grown for Seed Use Only as Non-Food or Food Uses

II Magnitude of the Residue: Post-harvest Fumigation of Crops and Processed Food and Feeds

III Magnitude of the Residue: Post-harvest Treatment (Except Fumigation of Crops and Processed Foods and Feeds

Data submitters can use the DRG in preparing their reports for submission to EPA to meet 40 CFR 158 requirements for the registration of pesticides. This DRG is only one of a number of DRG's published by the National Technical Information Service as an addendum to Subdivision O of the Pesticide Assessment Guidelines.

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b. Identifiers/Open-Ended Terms

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Subdivision O - Speciality Applications

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PESTICIDE ASSESSMENT GUIDELINES

RESIDUE CHEMISTRY

Specialty Applications

Subdivision O, Series 171-4

DATA REPORTING

FOREWORD

The Data Reporting Guidelines are addenda to the Pesticide Assessment Guidelines (Subdivision O), designed primarily to aid the petitioner/registrant in generating reports compatible with the Environmental Protection Agency's review process. They were intended also to clarify ambiguities in the interpretation of the existing Pesticide Assessment Guidelines.[1/] The Data Reporting Guidelines are not intended to introduce new data requirements or revisions to the Pesticide Assessment Guidelines, nor are they intended for use by Agency reviewers as a mere checklist. While following the Data Reporting Guidelines is not mandatory, data submitters are encouraged to submit complete reports which can be efficiently reviewed by the Agency. The Agency realizes there are sections in the Data Reporting Guidelines which do not apply in all cases. Therefore, registrants should exercise judgment in deciding which portions are germane to a specific data submission.

This guidance pertains to the substance of the data report. PR Notice 86-5, effective on November 1, 1986 (available from the Registration Support and Emergency Response Branch, Office of Pesticide Programs, US EPA), pertains to the physical formating of reports (which are referred to as "studies") and submittal packages. Some of the requirements in PR Notice 86-5 are mandatory.

The Data Reporting Guideline on Specialty Applications is divided into three parts: (I) Classification of Seed Treatments and Treatment of Crops Grown for Seed Use Only as Non-Food or Food Uses; (II) Postharvest Fumigation of Crops and Processed Foods and Feeds; (III) Post-harvest Treatment (Except Fumigation) of Crops and Processed Foods and Feeds. Each part gives the format/outline recommended by the Agency to be used by the petitioner/ registrant for reports on the particular specialty application study.

RESPONSE TO PUBLIC COMMENTS

The purpose of this section is to acknowledge and address the concerns expressed in the letters of comments received by the Agency in response to

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1/ In addition, Residue Chemistry Standard Evaluation Procedures, designed to aid Agency reviewers in their evaluations of pesticide residue data, are available. They provide a more thorough clarification of the existing Pesticide Assessment Guidelines.

the public notice in the FEDERAL REGISTER of October 15, 1986 (51 FR 36753). The only comment received concerning these guidelines was that the guidelines should not contain technical details on why the test is necessary, how it should be run and how the data will be evaluated; these should be covered by the Pesticide Assessment Guidelines and Standard Evaluation Procedures (SEPs). The Agency has included the introductory materials as a convenience to data submitters and to clarify relevant sections in the Pesticide Assessment Guidelines of difficulty for some registrants.

I

Classification of Seed Treatments and Treatment of Crops Grown for Seed Only as Non-Food or Food Uses

Treatment of Crops Grown for Seed Use Only

For the treatment of crops grown for seed use only to be classified as a non-food use, the following requirements must be met: (1) the seed itself or its sprouts are not raw agricultural commodities;[2] 2) there is no likelihood of residues in crops grown from harvested seed; (3) subsequent to treatment, all parts of the crop are not fit for human or animal consumption. Details of these requirements and any exceptions are given in Part I of the Standard Evaluation Procedure for Specialty Applications.[3] If the treatment of the crop grown for seed use only is classified as a non-food use, no residue studies are needed. If the treatment of the crop grown for seed use only is classified as a food use, metabolism and crop field studies are needed. The formats for the metabolism and crop field studies[4] are addressed in separate Data Reporting Guideline documents being developed concurrently, and the registrant/petitioner is referred to those Data Reporting Guidelines when the treatment of crops grown for seed use only is classified as a food use.

Seed Treatments

For seed treatments to be classified as a non-food use, data from a radiotracer study are needed demonstrating no uptake of radioactivity to the aerial portion and edible root (both human and livestock consumption) portion of the crop.[5] If the radiotracer study demonstrates that the particular seed treatment is a non-food use, no further studies are needed. If the seed treatment is classified as a food use, plant metabolism and crop field studies[4] are needed, and the registrant is referred to the Data Reporting Guidelines for those studies.

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[2] 40 CFR 180.1(e): Raw agricultural commodities include among other things fresh fruits, whether or not they have been washed and colored or otherwise treated in their unpeeled natural form; vegetables in their raw or natural state, whether or not they have been stripped of their outer leaves, waxed, prepared into fresh green salads, etc.; grains, nuts, eggs, raw milk, meats, and similiar agricultural produce. It does not include foods that have been processed, fabricated, or manufactured by cooking, freezing, dehydrating, or milling.

[3] The Standard Evaluation Procedure (SEP) for Specialty Applications is being developed concurrently.

[4] See Data Reporting Guideline for Magnitude of the Residue: Crop Field Trials; and Data Reporting Guideline for Nature of the Residue; Plants, available from the National Technical Information Service (NTIS), PB86-248192 and PB87-208641 respectively.

[5] For additional details, see Part I of the SEP for Specialty Applications.

The guideline given below in Part I of the Data Reporting Guideline for Specialty Applications is a format/outline for the radiotracer study determining whether or not the seed treatment results in uptake of radioactivity to the aerial edible and root portions of the crop. The report for this study should include all information necessary to provide a complete and accurate description of the study.

GUIDELINE

MASTER COVER PAGE

Title page and additional documentation requirements (i.e., requirements for data submission and procedure for claims of confidentiality of data) if relevant to the study report should precede the content of the study formatted below. These requirements are described in PR Notice 86-5.

TABLE OF CONTENTS

I. INTRODUCTION

A. Background and Historical Information on the Pesticide

1. Brief summary of nature of the residue in plants, including the structures of the parent and residues considered to be of toxicological concern;

2. Brief summary and references for residue data for the pesticide active ingredient on this commodity and related commodities available from other sources; and

3. List of current and former section 3, 5, 24(c) registrations and section 18 exemptions for the commodity under study and related commodities.

B. Purpose of Study

C. Abstract of Study

1. Brief summary of application and field procedures;

2. Results, including unexpected problems; and

3. Conclusions.

II. MATERIALS AND METHODS

A. Test substance

1. Identification of the test pesticide active ingredient (a.i.), including chemical name, common name (ANSI, BSI, ISO), registrant developmental/experimental name and chemical structure;

2. Description of the radiolabeled test material;

Identify the radiolabel and the site of the label. A rationale should be provided for selection of a radiolabel other than ^{14}C and for the site of the label (where possible the ring position should be labeled). The purity, specific activity in Curies/mole and disintegrations per minute per gram (dpm/g) should be reported here.

3. Identification of the pesticide formulated product(s) in which the radiolabeled pesticide active ingredient was applied, including trade name, type (EC, WP, G, etc.), pounds of active ingredient per gallon, percent a.i. by weight, EPA registration number, and manufacturer; and

4. Physical state and nature of the solvent, carrier, bait, adjuvant or other matrix in which the pesticide was applied.

B. Test Crop

Note: If more than one trial is carried out using different varieties, sites, etc., the registrant may prefer to include the following in Chapter IV, RAW DATA AND INFORMATION ON INDIVIDUAL FIELD TRIALS.

1. Identification of the test crop including variety and crop group classification according to 40 CFR §180.34(f), as revised June 29, 1983; 48 FR 29855;

2. Identification of specific crop part(s) harvested and subjected to analysis for radioactivity; and

3. Developmental stage(s), general condition (immature/mature, green/ripe, fresh/dry, etc.), size(s) of the test crop at time of harvest.

C. Test Site

Note: If more than one trial is carried out using different varieties, sites, etc., the registrant may prefer to include the following in Chapter IV, RAW DATA AND INFORMATION ON INDIVIDUAL FIELD TRIALS.

1. Description of test site;

Overall testing environment (outdoor test plots, greenhouse, plant growth chamber); location (county and state); environmental conditions (temperature, rainfall, sunlight); soil type;

2. Location (county, state); and

3. Cooperator.

D. Field Trial Methods

Note: If more than one trial is carried out using different

varieties, sites, cultural practices, etc., the registrant may prefer to include this in Chapter IV, RAW DATA AND INFORMATION ON INDIVIDUAL FIELD TRIALS.

1. Detailed description of application of radiolabeled pesticide to seeds:

   Information to be reported includes dose rate, pounds active ingredient and formulated product per pounds seed, concentration of treatment solution, volume of application solution per pounds seed, formulation, physical state in which pesticide is applied, diluent, additives, etc., method of application (hopper box, commercial equipment). The pesticide should be applied at the maximum proposed application rate.

2. Field trial lay-out:

   Information to be reported includes size of plots/pots, number of plants per plot/pot, number of plots/pots, number of plants per unit area, length of rows and row spacing.

3. Farming practice:

   Information on practices such as cultivation, irrigation, and treatments with other pesticides should be included here.

4. Harvest procedures, including the number of days between planting and harvesting.

E. Sampling, Handling and Storage

1. Dates of sampling, shipping, storage, and analyses;

2. Description of sampling procedure and size of samples; and

3. Handling, pre-shipping, shipping, post-shipping storage conditions, including storage times.[6/]

F. Analytical Procedures/Instrumention[7/]

1. Description of sample preparation (i.e., dissection, grinding, lyophilization, number of plants contained in one sample, etc.) prior to analyses of radioactivity; and

2. Details of analytical method to measure radioactivity, including descriptions of equipment and instrument parameters.

6/ Refer to the Data Reporting Guideline on Storage Stability available from NTIS, PB86-248192.

7/ Also refer to the Data Reporting Guideline on Analytical Methods available from NTIS, PB86-248192.

G. Quality Control

Description of control measures and precautions followed to ensure the fidelity of the field tests, samples and measurement of the residue.

H. Other Pertinent Information on Materials and Methods

III. RESULTS AND CONCLUSIONS

A. Brief Summary of Study Procedures

The summary of the study procedures should include the number of field trials, descriptions of the application of the radiolabeled pesticide to the seed (dose rate, method, formulation), the site (greenhouse, outdoors, plant growth chamber), number of days between planting and harvest, number of plants sampled, parts of the plant analyzed for radioactivity, and the method of detection.

B. Results

1. Total recovered (i.e., combustible) radioactivity on seeds at time of planting, if measured:

   The radioactivity should be reported as:

   a. disintegrations per minute (dpm)

   b. dpm/ug

   c. ppm equivalents (expressed as parent compound).

2. The distribution of radioactivity in the treated crop at the time of harvest or sampling:

   The data to be reported are the total recovered (i.e., combustible) radioactivity remaining at time of sampling or harvest on the whole plant and on the plants parts of interest; i.e., the aerial and edible root portions of the plant. The radioactivity for the whole plant and the plant parts should be reported in tabular format as:

   a. dpm

   b. dpm/ug

   c. ppm equivalents (expressed as parent compound).

   For the plant parts, the radioactivity should also be expressed as:

   d. The percentage of the total recovered radioactivity in the whole plant.

3. Graphs and figures of the results:

   Graphs, if provided, should be accompanied by tables of actual values from which graphs were constructed.

4. Narrative of results:

   Narrative should include a discussion of the quantitative accountibility for a majority of the total radioactivity recovered from the aerial and edible root portions of the plant and a discussion of unexpected problems, the way in which they were resolved, and explanations for apparently aberrant, atypical values.

C. Conclusions

The registrant's conclusion on whether or not the results of this study and any other relevant studies support a non-food use classification for the seed treatment in question should be given.

IV. RAW DATA AND INFORMATION ON INDIVIDUAL FIELD TRIALS

A. Details of Radioactive Counting Data for Selected Representative Samples

Details should include counting times, total counts recorded, corrected counts, counting efficiencies, other raw data (sample sizes, ppm equivalents found, sensitivity, limit of detection) and other pertinent information needed to check the registrant's calculations.

B. Description of Calculations, Including Examples

C. Description of Statistical Tests, Including Examples

D. Representative Raw Data Figures

As applicable, printout sheets, chromatograms, spectra, etc.

E. Detailed Descriptions of Each Field Trial

Note: Some of this information is the same included under Chapter II, MATERIALS AND METHODS. It is not necessary to include this in more than one location in the report. The registrant may decide where to report this information.

1. Information to be reported for each field trial includes:

   a. Test crop (see chapter II.B of this guideline);

   b. Test site (see chapter II.C of this guideline);

   c. Field trial methods (see chapter II.D of this guideline);

d. Dates (treatment of seeds, planting, sowing, transplanting, sampling/harvest, receipt in laboratory, storage, analysis, etc.);

e. Length of storage of samples; and

f. Sample identification.

F. Other

Any additional information the registrant considers appropriate and relevant to provide a complete and thorough description of the study.

V. CERTIFICATION

Certification of authenticity by the Study Director (including signature, typed name, title, affiliation, address, telephone number and date).

VI. REFERENCES

VII. APPENDICES

A. Reprints of published and unpublished literature, company reports, letters, etc., not expected to be in OPP files, but which the registrant feels will aid the review of the study.

B. Other pertinent information which does not fit in any other section of this outline.

II

Magnitude of the Residue: Post-harvest Fumigation of Crops and Processed Foods and Feeds

Part II of the Data Reporting Guideline for Specialty Applications is an outline/format for a report on a study to determine the magnitude of the residue which will result on raw crops and processed foods and feeds as a result of post-harvest fumigation. Other post-harvest treatments are the subject of Part III of this Data Reporting Guideline. Fumigation may be defined as the act of releasing and dispersing a toxic chemical so that it reaches the organism wholly or primarily in the gaseous or vapor state. Both the raw agricultural commodities and its processed products may be treated post-harvest by fumigation.

The report for a study on the post-harvest fumigation of raw crops and processed foods and feeds should include all information necessary to provide a complete and accurate description of the study. The study should answer the following question: what is the maximum level of "total toxic residue"[8/] that will result in or on the raw food or feed or processed food or feed from the proposed post-harvest fumigation of the raw or processed commodity with the pesticide formulated product? Actual residue data on commodities as consumed should be provided in cases where tolerance level residues lead to unreasonable risks. Crop group considerations should also be addressed, and an effort should be made to achieve harmonization with applicable International Residue Limits (Codex).

GUIDELINE

MASTER COVER PAGE

Title page and additional documentation requirements (i.e., requirements for data submission and procedure for claims of confidentiality of data) if relevant to the study report should precede the content of the study formatted below. These requirements are described in PR Notice 86-5.

TABLE OF CONTENTS

8/ The term "total toxic residue" is used to describe the sum of the parent and its degradation products, metabolites (free or bound), and impurities that are considered to be of toxicological significance, and therefore warrant regulation.

I. INTRODUCTION

A. Background and historical information on the pesticide

1. Brief summary of nature of the residue in plants, including the structures of the parent and the residues considered to be of toxicological significance;

2. Brief summary and references for residue data for the pesticide active ingredient on this commodity and related commodities, available from other sources; and

3. List of current or former section 3, 5, 24(c) registrations and section 18 exemptions for the pesticide active ingredient on the commodity under study or related commodities.

B. Purpose of Study

C. Abstract of Study

1. Brief summary of application procedures;

2. Results, including unexpected problems; and

3. Conclusions.

II. MATERIALS AND METHODS

A. Test Substance

1. Identification of the test pesticide active ingredient (a.i.), including chemical name, common name (ANSI, BSI, ISO), registrant developmental/experimental name and chemical structure;

2. Identification of the pesticide formulated product(s) in which the pesticide active ingredient was applied, including trade name, type (EC, WP, G, etc.), pounds of active ingredient per gallon, percent a.i. by weight, EPA registration number and manufacturer;

3. Information on the matrix in which the formulated pesticide was applied and on any additives; and

4. Physical/chemical parameters on the test substance.

B. Test Raw or Processed Commodity

Note: If more than one trial is carried out using different varieties, fumigation chambers, conditions, etc., the registrant may prefer to include the following in Chapter IV, RAW DATA AND INFORMATION ON INDIVIDUAL TRIALS.

1. Identification of the raw or processed test commodity, including variety and crop group classification according to 40 CFR §180.34(f), as revised June 29, 1983; 48 FR 29855;

2. Identification of specific crop part(s) harvested, fumigated and analysed;

3. Developmental stage(s), general condition (immature/mature, green/ripe, fresh/dry, etc.), size(s) of the test commodity at time of fumigation;

4. Size and kind of containers holding the commodity (e.g. wood burlap, etc.); and

5. Information on whether the raw or processed commodity, or its storage container, had been treated prior to the test post-harvest treatment, including application rates, PHI's and the residue prior to the test post-harvest treatment.

C. Test Site

Note: If more than one trial is carried out using different varieties, sites, etc., the registrant may prefer to include the following in Chapter IV, RAW DATA AND INFORMATION ON INDIVIDUAL TRIALS.

1. Description of fumigation chamber

Information to be reported includes:

a. Type of fumigation chamber (grain elevator and flat storage, tarpaulin covering, shophold, fumigation, vault, vacuum chamber, etc.);

b. Size and geometry of fumigation chamber;

c. Measures taken to seal the fumigation chamber (e.g., covering surfaces with asphalt paper or plastic tarpaulins, sealing of vents, windows, cracks, etc.);

d. Drafts inside the chamber;

e. Temperature inside the chamber; and

f. The relative size of the chamber as compared to the commodity load.

2. Location of fumigation chamber

Information to be reported includes:

a. County and state;

b. Environmental conditions (temperature, wind, temperature); and

c. Cooperator.

D. Application of the Pesticide

Note: If more than one trial is carried out using different varieties, fumigation chambers, conditions, etc., the registrant may prefer to include the following in Chapter IV, RAW DATA AND INFORMATION ON INDIVIDUAL TRIALS.

1. Type of fumigant dispensing system and method of fumigant volitilization;

2. Measures taken to hasten gas circulation;

3. Dose rate, exposure time, temperature, and pressure;

4. Layout of the fumigation (i.e., discharge points and positioning of circulating fans/blowers in relation to arrangement of commodities, size of stacks of commodities, etc.);

5. Number and date(s) of application(s); and

6. Formulation.

E. Aeration of the Commodities

1. The aeration time and the dates of the aeration;

2. Description of aeration procedures inside (e.g., removal of seals and covers, opening of doors and windows, use of exhaust fans and air suction systems) and outside the fumigation chamber; and

3. Description of any aeration following sampling.

F. Sampling, Handling, and Storage

1. Dates of sampling, shipping, storage and, analyses;

2. Description of sampling procedure, including the location of the sampling (e.g., top, bottom or side outer layer or center of stack; side or middle of chamber), size of the samples, and measures taken to prevent desorption of the fumigant during sampling; and

3. Handling, pre-shipping, shipping, and post-shipping storage conditions, including storage times[9/], special measures taken to prevent desorption of the fumigant during the time between sampling and analysis, and description of sample containers and storage temperature.

9/ See Data Reporting Guideline on Storage Stability available from NTIS, PB86-248192.

G. Analytical Procedures/Instrumention[10/]

1. Description of sample preparation (compositing, subsampling, grinding, extraction, etc.) and measures taken to prevent desorption of the fumigant during sample preparation; and

2. Details of analytical method to measure residue, including descriptions of equipment/instrumentation and instrument parameters.

H. Quality Control

Description of control measures and precautions to ensure the fidelity of the field test, samples and measurement of the residue.

I. Any Other Pertinent Information on Material and Methods

III. RESULTS AND CONCLUSIONS

A. Brief Summary of the Study Procedures

The summary of the study procedures should include the number of trials, the commodities, whether the commodities had been previously treated with the test active ingredient, descriptions of the fumigations and fumigation chambers, the formulation, aeration time, and the method of detection.

B. Results of Analyses of Treated and Control Samples and Fortified Samples

1. Tables of the results

Residue data should be given in a tabular format, providing the following information:

a. Commodity;

b. Plant part;

c. Type of fumigation chamber;

d. Dose;

e. Exposure time;

f. Temperature;

g. Aeration time; and

10/ Refer to the Data Reporting Guideline on Analytical Methods available from NTIS, PB86-248192.

h. Residue; residue testing should extend beyond sampling immediately after the label specified aeration to include studies to follow the rate of residue decline that could be expected under various shipping and storage conditions and temperature.

2. Graphs and Figures of the Results:

Graphs, if provided, should be accompanied by tables of actual values from which graphs were constructed.

3. Narrative on the results:

Narrative should include a discussion of unexpected problems and ways in which they were resolved and explanations for apparently aberrant, atypical values.

E. Conclusions on the Appropriate Tolerance(s) for the Proposed Use(s)

IV. RAW DATA AND INFORMATION ON INDIVIDUAL TRIALS

A. Raw Data Tables for Residue Analyses of Treated, Control and Fortification Recovery Samples and Standards

B. Representative Raw Data Figures

1. As applicable, printouts, spectra, chromatograms of treated samples, control samples, fortified samples and standards, etc.; and

2. Calibration curves.

C. Description of Calculations, Including Examples

D. Description of Statistical Tests, Including Examples

E. Detailed Descriptions of Each Trial

Note: Some of this information is the same included under MATERIALS AND METHODS (Chapter II of the format). It is not necessary to include this information in more than one location in the report. The registrant may decide where to report this information.

1. Information should be reported for each trial on:

a. Test raw or processed commodity (see Chapter II.B of this guideline);

b. Test site (see Chapter II.C of this guideline);

c. Application of the pesticide (see Chapter II.D of this guideline);

d. Aeration of the commodities (see Chapter II.E of this guideline);

e. Dates (fumigation, aeration, sampling, receipt at laboratory, analyses, etc.); and

f. Sample identification.

F. Other

Any additional information the registrant considers appropriate and relevant to provide a complete and thorough description of the study.

V. CERTIFICATION

Certification of authenticity by the Study Director (including signature, typed name, title, affiliation, address, telephone number and date).

VI. REFERENCES

VII. APPENDICES

A. Reprints of published and unpublished literature, company reports, letters, etc., not expected to be in OPP files, but which the registrant feels will aid the review of the study.

B. Other pertinent information which does not fit in any other section of this outline.

III

Magnitude of the Residue: Post-harvest Treatment
(Except Fumigation) of Crops and Processed Foods and Feeds

Part III of the Data Reporting Guideline for Specialty Applications is an outline/format for a report of a study to determine the magnitude of the residue which will result on raw crops and processed foods and feeds as a result of post-harvest treatments, except fumigation. Post-harvest fumigation is the subject of Part II of this Data Reporting Guideline.

Post-harvest treatments of foods and feeds are applied by various means, including dips, drenches, mechanical foamers, and spray and brush applicators. The pesticide may be applied directly (to the commodity) or indirectly (to the storage bin). Often, the application of a wax coating on the commodity is involved. Both the raw agricultural commodity and its processed product may be treated post-harvest. Additional details on post-harvest treatments are given in Part III of the Standard Evaluation Procedure for Specialty Applications.11/

The report for a study on the post-harvest treatment of raw crops and processed foods and feeds should include all information necessary to provide a complete and accurate description of the study. The study should answer the following question: what is the maximum level of "total toxic residue" that will result in or on the raw food or feed or processed food or feed from the proposed post-harvest treatment of the raw or processed commodity with the pesticide formulated product? Actual residue data on commodities as consumed should be provided in cases where tolerance level residues lead to unreasonable risks. Crop group considerations should also be addressed, and an effort should be made to achieve harmonization with applicable International Residue Limits (Codex).

GUIDELINE

MASTER COVER PAGE

Title page and additional documentation requirements (i.e., requirements for data submission and procedure for claims of confidentiality of data) if relevant to the study report should precede the content of the study formatted below. These requirements are described in PR Notice 86-5.

TABLE OF CONTENTS

11/ To be published.

I. INTRODUCTION

A. Background and Historical Information on the Pesticide

1. Brief summary of nature of the residue in plants, including the structures of the parent and the residues considered to be of toxicological significance;

2. Brief summary and references for residue data on this commodity and related commodities available from other sources; and

3. List of current or former section 3, 5, 24(c) registrations and section 18 exemptions for the commodity under study or related commodities.

B. Purpose of Study

C. Abstract of Study

1. Brief summary of application procedures;

2. Results, including unexpected problems; and

3. Conclusions.

II. MATERIALS AND METHODS

A. Test Substance

1. Identification of the test pesticide active ingredient (a.i.), including chemical name, common name (ANSI, BSI, ISO), registrant developmental/experimental name and chemical structure;

2. Identification of the pesticide formulated product(s) in which the pesticide active ingredient was applied, including trade name, type (EC, WP, G, etc.), pounds of active ingredient per gallon, percent a.i. by weight, EPA registration number and manufacturer; and

3. Information on the matrix (e.g., water, wax) in which the formulated pesticide was applied and on any additives.

Trade and chemical names for the matrix substance and additives should be provided.

B. Test Raw or Processed Commodity

Note: If more than one trial is carried out using different varieties, application procedures, conditions, etc., the registrant may prefer to include the following in Chapter IV, RAW DATA AND INFORMATION ON INDIVIDUAL TRIALS.

1. Identification of the raw or processed test commodity, including variety and crop group classification according to 40 CFR §180.34(f), as revised June 29, 1983; 48 FR 29855;

2. Identification of specific crop part(s) harvested, treated, and analysed;

3. Developmental stage(s), general condition (immature/mature, green/ripe, fresh/dry, etc.), size(s) of the test commodity at time of treatment; and

4. Information on whether the commodity or storage container had been treated with the test active ingredient prior to the test post-harvest treatment, including application rates, PHI's, and the residue prior to the test post-harvest treatment.

C. Test Site

Note: If more than one trial is carried out using different varieties, application procedures, conditions, etc., the registrant may prefer to include the following in Chapter IV, RAW DATA AND INFORMATION ON INDIVIDUAL TRIALS.

1. Description of test site;

Overall testing environment (outdoor, indoor, climate controlled packinghouse, etc.), temperature;

2. Location (county, state); and

3. Cooperator.

D. Application of the Pesticide

Note: If more than one trial is carried out using different varieties, application procedures, conditions, etc., the registrant may prefer to include this in Chapter IV, RAW DATA AND INFORMATION ON INDIVIDUAL TRIALS.

1. Physical state in which the pesticide was applied;

2. Description of method/equipment for pesticide application; e.g., direct (applied to commodity) or indirect (applied to storage container), dips, drenches, mechanical foamers, spray applicators, brush applicators, wax applicators;

3. Pounds active ingredient and formulation per pounds treated commodity, concentration of treatment solution, volume of treatment solution per pounds treated commodity, exposure time, number of treatments, temperature of solution;

4. Description of post-harvest practices accompanying the post-harvest treatment such as application of wax coatings after treatment,

detergent washes, and rinses, including number, timing, and volume;

5. Date(s) of application(s); and

6. Formulation.

F. Sampling, Handling and Storage

1. Dates of sampling, shipping, storage and analyses;

2. Description of sampling procedure and size of the samples; and

3. Handling, pre-shipping, shipping, and post-shipping storage conditions, including storage times[12/].

G. Analytical Procedures/Instrumention[13/]

1. Description of sample preparation (compositing, subsampling, grinding, extraction, etc.); and

2. Details of analytical method to measure residue, including descriptions of equipment/instrumentation and instrument parameters.

H. Quality Control

Description of control measures and precautions to ensure the fidelity of the field test, samples and measurement of the residue.

I. Any Other Pertinent Information on Material and Methods

III. RESULTS AND CONCLUSIONS

A. Brief Summary of Study Procedures

The summary of the study procedures should include the number of trials, the commodities, whether the commodities had been previously treated with the test active ingredient, description of the post-harvest treatment (e.g., concentration, exposure time, temperature), the formulation, and the method of detection.

B. Results of Analyses of Treated and Control Samples and Fortified Samples

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12/ See Data Reporting Guideline on Storage Stability available from NTIS, PB86-248192.

13/ See Data Reporting Guideline on Analytical Methods available from NTIS, PB86-248192.

1. Tables of the results

Residue data should be given in a tabular format, providing the following information, as applicable:

a. Commodity;

b. Plant part;

c. Method/equipment for pesticide application;

d. Pounds active ingredient per pounds commodity;

e. Concentration of treatment solution;

f. Volume treatment solution per pounds commodity;

g. Exposure time;

h. Number of treatments;

i. Other pertinent information affecting the level of residue (e.g., use of wax, rinse, volume and time of rinse);

j. Formulation; and

k. Residue; residue testing should provide information on the rate of residue decline that could be expected under various shipping and storage conditions and temperature.

2. Graphs and figures of the results:

Graphs, if provided, should be accompanied by tables of actual values from which graphs were constructed.

3. Narrative on the results:

Narrative should include a discussion of unexpected problems and ways in which they were resolved and explanations for apparently aberrant, atypical values.

C. Conclusions on the Appropriate Tolerance(s) for the Proposed Use(s)

IV. RAW DATA AND INFORMATION ON INDIVIDUAL TRIALS

A. Raw Data Tables for Residue Analyses of Treated, Control and Fortification Recovery Samples, and Standards

B. Representative Raw Data Figures

1. As applicable, printouts, spectra, chromatograms of treated samples, control samples, fortified samples and standards, etc.; and

2. Calibration curves.

C. Description of Calculations, Including Examples

D. Description of Statistical Tests, Including Examples

E. Detailed Descriptions of Each Trial

Note: Some of this information is the same included in Chapter II, MATERIALS AND METHODS. It is not necessary to include this information in more than one location in the report. The registrant may decide where to report this information.

1. Information to be reported for each trial includes:

a. Test raw or processed commodity (see chapter II.B of this guideline);

b. Test site (see chapter II.C of this guideline);

c. Application of the pesticide (see chapter II.D of this guideline);

d. Dates (treatment, sampling, shipping, receipt in laboratory, storage, analyses, etc.);

e. Length of storage of samples; and

f. Sample identification.

F. Other

Any additional information the registrant considers appropriate and relevant to provide a complete and thorough description of the study.

V. CERTIFICATION

Certification of authenticity by the Study Director (including signature, typed name, title, affiliation, address, telephone number and date).

VI. REFERENCES

VII. APPENDICES

A. Reprints of published and unpublished literature, company reports, letters, etc., not expected to be in OPP files, but which the registrant feels will aid the review of the study.

B. Other pertinent information which does not fit in any other section of this outline.